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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,385	07/27/2001	Lisa A.G. Twardy	1461-R-00	9974
7590	10/24/2003			
			EXAMINER	
			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,385	TWEARDY, LISA A.G.	
Examiner	Art Unit		
Julian W. Woo	3731		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer (5,042,462) in view of Spetzler (5, 669,912). Bremer discloses the

invention substantially as claimed. With respect to claims 1-4 and 7-13, Bremer discloses, in figure 4 and in col. 3, line 46 to col. 4, line 11, a skull pin with a pin body (23) having a bore and a rounded pin tip (26) formed of electrical insulating material or ceramic material ("single crystal alumina ceramic"), where the pin tip consists of a cylindrical, straight-sided portion and a tapered portion. Also, with respect to claims 7-13, Bremer discloses a kit with the skull pin and a halo (10) or skull tongs. However, Bremer does not disclose that the rounded tip of the pin has a radius in the range of .025 to .075 mm. And with respect to claim 5, Bremer does not disclose a pin tip with a bore for receiving the pin body. Spetzler teaches, in col. 3, lines 23-35, a skull pin with a diameter of approximately .1 mm (i.e., a radius of .050 mm) at its tapered end (17 or 18). It would have been obvious to one having ordinary skill in the art at the time the invention, in view of Spetzler, to size the rounded tip of Bremer's pin, so that it has a radius of .050 mm or in the range of .025 to .075 mm. Such dimensions at the tip present an area for engagement (a point) sufficient for bone penetration. Also with respect to claim 5, the reversal of the pin tip with a bore for receiving the pin body and the pin body with a bore for receiving the pin tip (as in claim 4) is an obvious reversal of engaging parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a pin tip with a bore for receiving the pin body interchangeably with a pin body with a bore for receiving the pin tip. The reversal of engaging parts would be dependent upon the particular application of the pin and the sizes of the pin components desired for the application.

4. Claim 6, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer in view of Spetzler as applied to claims 1, 7, and 9 above, and further in view of Iversen et al. (6,045,553). Bremer in view of Spetzler discloses the invention substantially as claimed but does not disclose that the tapered portion has an angle between 30 deg. and 50 deg. Iversen et al. teach, in fig. 6 and in col. 4, lines 40-44, a skull pin with a tapered portion having an angle of approximately 40 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Iversen et al., to dimension the tapered portion of the pin of Bremer in view of Spetzler, so that has angle of approximately 40 degrees or within the range between 30 deg. and 50 deg. Such an angle presents a tip configuration sufficient for skull engagement.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer in view of Iversen et al. Bremer discloses a skull pin substantially as claimed, but does not disclose that the tapered portion has an angle between 30 deg. and 50 deg. Iversen et al. teach, in fig. 6 and in col. 4, lines 40-44, a skull pin with a tapered portion having an angle of approximately 40 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Iversen et al., to dimension the tapered portion of the pin of Bremer, so that has angle of approximately 40 degrees or within the range between 30 deg. and 50 deg. Such an angle presents a tip configuration sufficient for skull engagement.

Response to Amendment

6. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Also with respect to the arguments regarding rejections based on the Bremer references (4,612,930 and 5,042,462): "Pointed" is a relative term referring to the radial narrowness of the pin tip or tapered portion with respect to the rest of the pin. That is, the tip of Bremer's pin is "pointed" and rounded (analogous to, e.g., a ball-point pen). With respect to arguments based on "Exhibit A" (4,612,930, fig. 3), the angle of the tip cannot be accurately gleaned from a figure meant to be a rendering of the invention and not meant to be an engineering drawing.

Additionally, the declaration under 37 CFR 1.132 filed July 17, 2003 is insufficient to overcome the rejection of claims 1-16 based upon Bremer (5,042,462) as set forth in this Office action and the last Advisory Action, because it declares the efficacy of the claimed range of angles for the tapered portion of the Applicant's pin, but it does not negate other angles disclosed by the prior art of record, where other angles are also shown to be effective for skull or bone penetration.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jonas et al. (2,672,861) teach a bone pin with a pointed and rounded tip. Clemow et al. (4,858,603) teach a bone pin with a tip having a bore for receiving a pin body. Huebner (5,868,789) teaches an anchor with a tip portion having a range of angles.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

October 22, 2003